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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,215	03/27/2001	Scott A. Waldman	100051.11401(TJU0014-100)	2195

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Pepper Hamilton LLP  
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EXAMINER
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CALAMITA, HEATHER

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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05/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<p><b>Application No.</b> 09/820,215</p>	<p><b>Applicant(s)</b> WALDMAN ET AL.</p>	
	<p><b>Examiner</b> HEATHER G. CALAMITA</p>	<p><b>Art Unit</b> 1637</p>	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 23 April 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_.
- Claim(s) objected to: \_\_\_\_\_.
- Claim(s) rejected: 1,4,6-11,13-15 and 37-53.
- Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_
13. ☐ Other: \_\_\_\_\_.

/GARY BENZION/  
Supervisory Patent Examiner, Art Unit 1637

Continuation of 11. does NOT place the application in condition for allowance because: With respect to the written description rejections of claims 1, 4, 6-11, 13-15 and 37-47, Applicants' arguments have been considered but are not persuasive. Applicants argue the rejection is not supported by the Official Action. This is not persuasive because the burden has been met. As outlined in the rejection in the office action mailed January 23, 2008, Applicants are claiming a genus which comprises a class of compounds (mRNAs) that share a function (encoding a disseminated epithelial cell marker, wherein the marker is a differentiation-specific antigen). However, the specification does not specify a common structure of this class of mRNAs. That is, while the members of the genus encompassed by the claims (e.g., the mRNA encoding a disseminated epithelial cell marker, wherein the marker is a differentiation-specific antigen), share a function, they do not share a structure that is similar. Each mRNA encompassed by the genus will have different structure, absent any disclosed structural similarities provided by the specification. Additionally, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties", not a mere wish or plan for obtaining the claimed chemical invention". Applicants' specification offers no such description. Additionally, it was determined if a representative number of species have been described by their complete structure. In the instant case, the specification teaches a total of 26 epithelial cell markers and asserts these epithelial cell markers "can be" used as disseminated markers (see page 12, lines 10-27). However, these markers are not structurally related, nor do they share any common sequences, and therefore, these eight species are not considered to be a representative number of species. It is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g., similar structural motifs, sequence similarity, etc.). In the instant case, no such identifying characteristics have been provided for any of the claimed nucleic acids. Furthermore, it is noted that the specification does not describe which mRNA are specific for which "differentiation-specific antigen". In other words, the specification does not describe which mRNAs are specific for a particular tissue-specific marker. These 26 markers are in no way representative of the entire genus which comprises all of the known human genes in the genome. These 26 markers constitute less than 0.2 %. Applicants argued that a more realistic estimate should be based upon the number of differentiation-specific antigens which are known to be expressed in epithelial cells. Applicants however do not give any indication as to how to arrive at this number. There is nothing in the instant specification to define what specifically constitutes a differentiation-specific antigen. Applicants merely assert that the number of differentiation-specific antigens would be dramatically lower than that of all known genes. This assertion however is not persuasive because the genus is any expressed human protein and Applicants do not give any common structure or structure function correlation that allows one of skill in the art to determine if they are in possession of a differentiation specific antigen. With respect to the 103 (a) rejections, Applicants' argument is similar to that filed on October 31, 2008, and as such the rejections are maintained for reasons already of record (Office Action mailed January 23, 2008).